BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SP Europe submitted on 8 January 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Temodal, through the centralised procedure. After agreement by the CPMP in November 1996, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: A. Hildebrandt Co-Rapporteur: B. Odlind

Licensing status

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 30 January 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP members on 10 April 1998. The Rapporteur's first assessment report was circulated to all CPMP members on 16 April 1998.
- During the meeting on 26-27 May the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 28 May 1998.
- The company submitted the responses to the consolidated list of questions on 10 July 1998.
- The Rapporteur circulated the joint response assessment report on the company’s responses to the list of questions to all CPMP Members on 1 September 1998.
- The CPMP, during its September 1998 plenary meeting, adopted a list of outstanding issues to be addressed by the by the applicant in an oral explanation at the October CPMP meeting.
- A joint Rapporteur’s and Co-Rapporteur’s statement on the benefit/risk assessment was circulated to all CPMP members on 17 September 1998.
- Oral explanations were given by the applicant on 20 October 1998.
- During the meeting on 20-22 October 1998 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation for Temodal on 22 October 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding decisions on 20 January 1999.